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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,101	09/26/2005	Richard Mueller	ZP192-05009	1624

22884 7590 06/07/2011
MIDDLETON & REUTLINGER
2500 BROWN & WILLIAMSON TOWER
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LOUISVILLE, KY 40202

EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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06/07/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOmail@MiddReut.com

Office Action Summary	Application No. 10/551,101	Applicant(s) MUELLER, RICHARD	
	Examiner Nicholas Woodall	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,10,11,13-59 and 61-68 is/are pending in the application.
- 4a) Of the above claim(s) 16-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,10,11,13,14,55-59 and 61-68 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on August 23, 2010.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the post being symmetrical about a longitudinal axis extending centrally through the post and the post being asymmetrical about a longitudinal axis extending centrally through the post must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide antecedent basis for the limitations of claims 56, 57, 63, and 64 directed to the post being symmetrical about a longitudinal axis that extends centrally through the post.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 58, 59, 65, and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure as originally filed does not comply with the written description for the limitations directed to the post being asymmetrical about a longitudinal axis that extends centrally through the post.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 10, 55-57, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker (U.S. Patent 6,660,004) in view of Vienney (WO 03/024343) and in view of Puno (U.S. Patent 5,360,431).

Barker discloses a device (see Figure 7 for an example) comprising a polyaxial bone screw (50), a rod (R) having a diameter defining a first dimension, a housing (30, 70, 90, etc.), and a locking assembly (120). The bone screw includes a proximal end that engages a driving device and a distal end that engages bone. The proximal end of the bone screw includes a head having an aspheric upper surface, i.e. the specification discloses the upper surface of the head may only have knurls or a roughened surface (column 5 lines 43-45) proving an aspheric surface, i.e. not perfectly sphere shaped. The housing is coupled to the proximal end of the bone screw and includes opposing spaced apart flanges that extend longitudinally and define a channel that receive the rod. The flanges include an outer surface and an inner surface with female threads on a portion of the inner surface. The locking assembly locks the rod to the housing in contact with the proximal end of the bone screw. The rod is inserted into the channel of the housing and the locking assembly is inserted into the channel of the housing, wherein a driving instrument is inserted into the cavity of the locking assembly and rotates the locking assembly thereby engaging at least a portion of a male thread with the female threads of the housing causing the locking assembly to translate longitudinally into the housing and in contact with the rod, which forces the rod into a

locked relationship with the proximal end of the bone screw to prevent angular movement of the bone screw relative to the housing (see column 8 lines 28-37). Barker fails to disclose the device having a locking assembly that includes an upper cap and a lower cap and the lower cap of the locking assembly including an extension.

Regarding the locking assembly including an upper cap and a lower cap, Barker discloses a device comprising a locking assembly as discussed above. Vienney teaches a device (see Figure 1 for an example) comprising a bone anchor integrally formed with a housing having an inner surface with female threads, a rod, and a locking assembly, wherein the locking assembly includes an upper cap (4) having male threads (41) and an inner cavity having a second profile passing through the upper cap from a upper surface to a lower surface that includes an opening to receive a post (33) having a first profile that is geometrically similar to the second profile (see Figure 5), a lower cap (3) having a lower semi-cylindrical surface that engages the rod, wherein the post joins the upper cap to the lower cap and allows free rotational movement of the caps relative to one another such that a driving instrument inserted into the inner cavity rotates the upper cap relative to the lower cap about the post to engage the male threads with the female threads to longitudinally translate the locking assembly within the housing and into contact with the rod in order to force the rod into a locked relationship with the housing. Because both Barker and Vienney teach devices including locking assemblies positioned within a housing to force a rod into a locked relationship with the housing, it would have been obvious to one having ordinary skill in the art at the time the invention

was made to substitute one locking assembly for the other in order to achieve the predictable results of forcing a rod into a locked relationship with the housing.

Regarding the lower cap including an extension, Puno teaches a device (see Figures 4-7 for an example) comprising a bone anchor, a housing including opposing flanges defining a channel, and a locking assembly, wherein the locking assembly includes an upper cap (27) and a lower cap (25) having a semi-cylindrical surface (72) that engages a rod and an integral extension (46/47) that protrudes from the lower cap into the channel of the housing and includes an extension of the semi-cylindrical surface in order to help align the lower cap relative to the rod. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Barker as modified by Vienney wherein the lower cap further includes an extension in view of Puno in order to help align the lower cap relative to the rod.

Regarding the upper cap and the lower cap being received within the housing in no more than two orientations, the Puno reference discloses the lower cap having two extension that help align the lower cap with the rod and will only allow the lower cap into the housing if the extensions are aligned within the channel, which also allows the upper cap to only engage the threads of the housing when the lower cap is properly aligned with the housing. Therefore, the device of Barker as modified by Vienney as further modified by Puno discloses a device wherein the lower cap can inserted into the housing in no more than two orientations.

Regarding the post being symmetrical about a longitudinal axis/plane, the claims are not specific on which longitudinal axis/plane the post is symmetrical about. Vienney

teaches a post that has a longitudinal axis/plane that is perpendicular to the longitudinal axis/plane of the rod. Therefore, the device of Barker as modified by Vienney as further modified by Puno discloses a device wherein the post is symmetrical about a longitudinal axis/plane.

8. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker (U.S. Patent 6,660,004) in view of Vienney (WO 03/024343) further in view of Puno (U.S. Patent 5,360,431) further in view of Tsou (U.S. Patent 5,176,678).

The device of Barker as modified by Vienney as further modified by Puno discloses the invention as claimed except for the bone anchor comprising a hook. The device of Barker as modified by Vienney as further modified by Puno discloses a device comprising a bone screw as discussed above. Tsou teaches a device comprising a bone anchor, a rod, a housing, and a locking assembly, wherein the bone anchor can be either a polyaxial bone screw or a polyaxial hook in order to anchor the device to a bone. Because both the device of Barker as modified by Vienney as further modified by Puno and the device of Tsou both disclose bone anchors for anchoring a device to a bone, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one bone anchor, i.e. a bone screw, for the other, i.e. a hook, in order to achieve the predictable results of anchoring the device to a bone.

9. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker (U.S. Patent 6,660,004) in view of Vienney (WO 03/024343) further in view of Puno (U.S. Patent 5,360,431) further in view of Katz (U.S. Patent 5,989,254).

The device of Barker as modified by Vienney as further modified by Puno discloses the invention as claimed except for the proximal end of the bone screw further comprising a depression disposed about the periphery, i.e. intersection of the upper and lower surfaces of the head of the bone screw and the inner cavity further comprising an appurtenance projecting substantially radially inward. Katz teaches a device (see Figure 1) comprising a bone screw with a head, a rod, a locking assembly with a lower cap (16) and an upper cap (15), and a housing including flanges defining a channel and an inner cavity, wherein the bone screw head further includes a depression disposed about a periphery of the head and the inner cavity further includes an appurtenance that projects substantially radially inward into the depression in order to retain the housing on the screw during implantation (see column 2 lines 61-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Barker as modified by Vienney as further modified by Puno wherein the head of the bone screw further comprises a depression and the inner cavity of the housing further comprises an appurtenance in view of Katz in order to retain the housing on the screw during implantation.

10. Claims 4, 11, 62-64, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker (U.S. Patent 6,660,004) in view of Puno (U.S. Patent 6,565,565).

Barker discloses a device (see Figure 7 for an example) comprising a polyaxial bone screw (50), a rod (R) having a diameter defining a first dimension, a housing (30, 70, 90, etc.), and a locking assembly (120). The bone screw includes a proximal end

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that engages a driving device and a distal end that engages bone. The proximal end of the bone screw includes a head having an aspheric upper surface, i.e. the specification discloses the upper surface of the head may only have knurls or a roughened surface (column 5 lines 43-45) proving an aspheric surface, i.e. not perfectly sphere shaped. The housing is coupled to the proximal end of the bone screw and includes opposing spaced apart flanges that extend longitudinally and define a channel that receive the rod. The flanges include an outer surface and an inner surface with female threads on a portion of the inner surface. The locking assembly locks the rod to the housing in contact with the proximal end of the bone screw. The rod is inserted into the channel of the housing and the locking assembly is inserted into the channel of the housing, wherein a driving instrument is inserted into the cavity of the locking assembly and rotates the locking assembly thereby engaging at least a portion of a male thread with the female threads of the housing causing the locking assembly to translate longitudinally into the housing and in contact with the rod, which forces the rod into a locked relationship with the proximal end of the bone screw to prevent angular movement of the bone screw relative to the housing (see column 8 lines 28-37). Barker fails to disclose the device having a locking assembly that includes an upper cap and a lower cap and the lower cap of the locking assembly including an extension.

Regarding the locking assembly including an upper cap and a lower cap, Barker discloses a device comprising a locking assembly as discussed above. Puno teaches a device (see Figures 15-16 for an example) comprising a bone anchor integrally formed with a housing having an inner surface with female rotational locking recesses, a rod,

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and a locking assembly, wherein the locking assembly includes an upper cap (220a) having male locking wings (284 and 286) and an inner cavity having a second profile passing through the upper cap from a upper surface to a lower surface that includes an opening to receive a post (298) having an uninterrupted periphery and a first profile that is geometrically similar to the second profile (see Figure 16), a lower cap (220b) having a lower semi-cylindrical surface that engages the rod and an integral extension (see Figure 15) that protrudes from the lower cap and is dimensioned to fit within the channel of the housing with a width substantially similar to the channel, wherein the post joins the upper cap to the lower cap and allows free rotational movement of the caps relative to one another such that a driving instrument inserted into the inner cavity rotates the upper cap relative to the lower cap about the post to engage the male locking wings with the female locking recesses to longitudinally translate the locking assembly within the housing and into contact with the rod in order to force the rod into a locked relationship with the housing. It would have been obvious to one having ordinary skill in the art to provide the device of Barker wherein the locking assembly further includes a lower cap in view of Puno in order to force the rod into a locked relationship with the housing.

Regarding the upper cap and the lower cap being received within the housing in no more than two orientations, the Puno reference discloses the lower cap having an extension that help align the lower cap with the rod and will only allow the lower cap into the housing if the extension is aligned within the channel, which also allows the upper cap to only engage the threads of the housing when the lower cap is properly aligned

with the housing. Therefore, the device of Barker as modified by Puno discloses a device wherein the lower cap can be inserted into the housing in no more than two orientations.

Regarding the post being symmetrical about a longitudinal axis/plane extending centrally through the post, Puno teaches a post that has a longitudinal axis/plane that extends centrally through the post and is perpendicular to the longitudinal axis/plane of the rod. Therefore, the device of Barker as modified by Puno discloses a device wherein the post is symmetrical about a longitudinal axis/plane that extends centrally through the post.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barker (U.S. Patent 6,660,004) in view of Puno (U.S. Patent 6,565,565) further in view of Tsou (U.S. Patent 5,176,678).

The device of Barker as modified by Puno discloses the invention as claimed except for the bone anchor comprising a hook. The device of Barker as modified by Puno discloses a device comprising a bone screw as discussed above. Tsou teaches a device comprising a bone anchor, a rod, a housing, and a locking assembly, wherein the bone anchor can be either a polyaxial bone screw or a polyaxial hook in order to anchor the device to a bone. Because both the device of Barker as modified by Puno and the device of Tsou both disclose bone anchors for anchoring a device to a bone, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one bone anchor, i.e. a bone screw, for the other, i.e. a hook, in order to achieve the predictable results of anchoring the device to a bone.

Allowable Subject Matter

12. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments filed August 23rd, 2010 have been fully considered but they are not persuasive. The applicant's arguments that the lugs of Vienney fail to disclose a post as claimed is not persuasive. The lugs of the Vienney reference define a post having an outer periphery defining a first profile that is similar to the profile of the opening of the upper cap to rotationally couple the two elements together. Claims 1-3, 10, 55-57, and 61 do not have any limitations that differentiate the post defined by the lugs of the Vienney reference from the post as claimed. The applicant's argument that the Barker reference does not disclose the rod being in contact with the head of the bone screw is not persuasive. The claims do not require the rod to be in contact with the bone screw. Claim 1 recites that the locking assembly locks the rod to the housing in contact with the proximal end of the anchor. Therefore, the claim only requires that the rod be locked to the housing that is in contact with the proximal end of the anchor. The applicant's argument that the references do not disclose the timing features of the locking mechanism, i.e. the starting threads that engage when the extension is in the channel, is not persuasive. First, the threads of the set screw (120) and the flanges have starting threads otherwise the elements would be able to thread to each other. Second, if the lower cap of the Puno reference is aligned such that the extension is not

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in the channels, then the upper cap is unable to interact with the flanges of the housing and therefore cannot properly engage each other. Only when the extension is in the channel can the upper cap and the flanges of the housing properly engage each other. Therefore, the device of Barker as modified by Puno discloses the invention as claimed. The applicant's argument that the second profile does not have two or less orientations relative to the first profile that allows the upper cap to be received in the housing is not persuasive. Both Puno reference disclose a lower cap having at least one extension. The extension can only be received in the channels in two orientations. If the extensions are not aligned with the channels then the upper cap cannot be received within the housing. The remaining arguments are directed to the claim amendments which have been addressed in the new grounds of rejection provided above. The examiner has provided new grounds of rejection as necessitated by the amendments making this office action **FINAL**.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Primary Examiner, Art Unit 3775